

Advisory Committee on Blood Safety and Availability

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**Representing The American Society for
Reproductive Medicine and The Society of
Assisted Reproductive Technologies**

Advisory Committee

- **American Society for Reproductive Medicine (ASRM)**
 - Includes many subgroups of reproductive medicine
- **Society of Assisted Reproductive Technologies**
 - Focuses on assisted reproductive technologies (ART), primarily in vitro fertilization which includes sexually intimate couples (~93% of all treatment cycles) and donation cycles (sperm, eggs, embryos)
 - >100,000 treatment cycles per year in US (total cycles)

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■ Reproductive Tissues

– Sperm

- (Primarily commercial agencies)

– Eggs (Oocytes)

- (Primarily by ART programs)
- Some commercial agencies

– Embryos

- ART Programs
- Non-profit “adoption” agencies
- Storage facilities that perform donor eligibility

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■ Current Oversight

– Medical

■ Physician Licensing

■ Federally mandated cycle reporting to CDC

- Joint validation effort between CDC & SART

– Laboratory

■ CLIA

■ Inspection agencies

- State
- College of American Pathologists
- Joint Commission for Health Care Organizations

– Both

■ FDA

- Donor eligibility determination

■ Professional organizations

- ASRM/SART

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- **Specific disease prevention Issues**
 - **SART Guidelines for donor testing**
 - **Specific for sperm, eggs, embryos**
 - **In some instances, more stringent than FDA**
 - Testing of recipient as well as donor
 - **FDA**
 - **Specific for sperm, eggs, embryos**
 - Donor eligibility determination
 - Screening and testing, time frames for both
 - **SART has requested an FDA liaison to develop uniform donor questionnaire**

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■ FDA Inspections

– Donor eligibility determination

- ART programs subject to FDA Regs as of 5/25/05
- As of 1/07, ~30% programs had been inspected
- Action rates similar to other fields

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■ Areas of concern

– False positive test results & re-entry criteria

- Known false positive results in exclusion

- No re-entry criteria

- Especially critical with egg donors

 - Limited number of donors

 - Limited number of cycles/donor

– Extra cost to patients

- Most patients pay out of pocket for care

- Even small increases are important

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■ Risk Estimate

– Low

- Gametes/embryo status as disease vector not known (i.e. washed semen as opposed to sperm)
- In couples known to be discordant for disease (HIV), risk of transmission <5% with appropriate oversight
 - Insemination, not ART cycles

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- **Ethical Implications for embryos**
 - Embryos stable for at least decades
 - Most embryos for donation are from couples that have completed their family building
 - If requirements for embryo donation are too restrictive it will result in many embryos being discarded as opposed to being donated to couples in need
 - Estimate of >500,000 embryos currently in storage
 - Majority for future use by couples that produced them